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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,089

09/09/2003

Mark A. Reiley

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06/19/2009

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,089	<b>Applicant(s)</b> REILEY, MARK A.	
	<b>Examiner</b> CHRISTOPHER D. PRONE	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 50-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/14/07 11/05/07  
4/25/08 10/6/08 2/24/09.

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-53 are pending, Claims 50-53 are withdrawn from consideration, and claims 1-49 are pending for consideration.

### ***Response to Arguments***

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. The applicant argues that the 112 rejection over claims 19-32 is improper. However the language of claims 19-32 does not disclose any actual structure or structural limitations. The language is merely intended use, which would be given more weight only in method claims. In their current form the claims are reciting the applicant's intended use for the device including its placement and replacement of components. This use language fails to define structural elements or limitations.

Examiner maintains that the claims in the current broad form are properly rejected by the cited prior art. Each reference independently shows a prosthesis comprising a prosthesis body including a fastening element that is to be installed within a bony body including an artificial facet joint structure carried by the body spaced from the fastening element where the facet joint is configured to replace all or a portion of the natural joint. By viewing the figures of each reference it is abundantly clear what can be considered the body, the fastening element, and the spaced apart joint.

In response to the applicants arguments directed at the 102/103 rejection, the examiner admits that the recitation of the prosthesis to be used to replace all or a

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portion of the natural facet joint on a vertebral body is not specifically disclosed in any of the applied references. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use it reads on the claim. It is the examiner's contention that the devices of the applied references do set forth structure that is capable of performing the intended function, i.e. prosthesis to replace all or a portion of a natural facet joint on a vertebral body. Because the art of record contains all the structure recited within the claims and has an overall general similar structure it is inherent that they could function as required by the claims, which the applicant has failed to point out any factual reasoning to the contrary. Applicant is advised to present factual evidence, not opinions to dismiss the art of record from being able to perform as claimed.

In order to advance prosecution the applicant is advised to drop the recitations of use and add language defining structural elements differentiating its device from the art of record.

### ***Claim Rejections - 35 USC § 112***

Claims 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adapted and configured" in the claims is a relative term which renders the claim indefinite. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language absent structural features relies solely on a functional use (ie. to replace a certain anatomical feature. The elected invention is directed to figure 24 and description of the elected illustrated device is found on pages 22-25 of the specification. Claim 1 positively sets forth structural elements of two body and two facet joint structures. However, claim the dependent claims 19-32 fail to positively set forth structure that would function after the removal of at least some of the lamina or other portions of the spinal process from the vertebral body. It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some of the lamina or the other structures of the spinal process.

The same argument is applicable for the subject matter set forth in each of the dependent claims 20-32.

Applicant's argues:

**Finally, there can be no serious argument that a skilled artisan would not understand the scope of each of claims 19-32 simply because of the use of the structural limitation "adapted and configured" in the claims. When read in light of the specification, the scope of each of these claims is clear. There is no need for these claims to specifically recite any more structure than each of them already does in order to meet the requirements of § 112. The Examiner's rejection of claims 19-32 under § 112, second paragraph, is inappropriate and should be withdrawn.**

Applicant's statement remains unpersuasive. Applicant has not set forth portions of the specification that define the various structures that would provide the function of the implant after removal or modification of some lamina or other portions of the vertebral bodies.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin [WO 95/05783].

Martin discloses a spinal fixation device comprising a fastening element, and an artificial joint structure carried by the fastening element. With respect to claim 33, the left and right joint structures are connected by a connecting element. See figures 1 and 11.

Claims 1-4, 12-18, 34-38, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Zang et al (5314486), Wall [4693722], Homsy et al [4778472] and Morgan [4917701].

Each prior art individually discloses a prosthesis comprising a fastening element, and an artificial joint structure carried by the fastening element. While the prosthesis of

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each prior art is intended for replacement of another type of joints, the structure as broadly claimed is fully met by each of the applied prosthesis. Each prosthesis is structurally similar to that as illustrated by applicant and therefor, examiner contends that each device is capable of performing the function of replacing all or a portion of the natural facet joint. Each prosthesis may be employed on either the right or left portion of the vertebral body.

Claims 2-4, each claim as worded is directed to a surgical step of attaching the assembly to the body and the language of the claims fail to further define positive structures for performing the claimed method step. Moreover, the prior art shows various means for attaching the prosthesis including, adhesive and mechanical attachment, respectively.

Claims 12, 13, 14, 15, 16, and 46 see prosthesis of any of Zang, et al, Wall [4693722], Homsy et al [4778472] and Morgan [4917701]. With respect to claims 12 and 46, if left and right facet structures are attached to the respective left and right portions of the vertebral body, then one facet will pivot with respect to the other facet joint, as broadly claimed.

Claims 17 as worded is directed to a surgical step of attaching the assembly to the spinal structure and the language of the claims fail to further define positive structures for performing the claimed method step. Moreover, the prior art shows various means for attaching the prosthesis to the bone structure including, adhesive and mechanical attachment, respectively.



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Claim 34 see rejection to claim 1 and any fastening elements in any of Wall, Homsy et al and Morgan.

Claims 35-38, see rejection to claims 2-4 supra.

Claim 47, each prosthesis of the cited references is designed to engage the opposite joint structure of the bone comprising the total anatomical joint.

Claims 18, 48, and 49, see materials as set forth in each reference as applied in claim 1. For example, see Zang, et al wherein the prosthesis is fabricated from selected biocompatible materials including titanium, cobalt chrome and may be fastened to the bone by with roughen surface providing a bone in-growth surface medium.

Claims 19-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4693722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486].

The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language, absent structural features, relies solely on a functional use (ie. to replace a certain anatomical feature). It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-17. It is not clear how each claim further defines the body and joint structure of claim 1 that would be reasonably clear to one of ordinary skill in the art.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zang, et al (5314486) as applied to claim 1 above, and further in view of Johnson et al (5609641).

The combination of the fastening element and the facet joint structure of Zang et al is illustrated to be one piece. It is well known in the art to fabricate the elements, fastening and the joint structure independently to be joined later by the surgeon, as shown for example by Johnson, et al. Independent elements allow for better sizing and matching of the prosthesis to the in vivo bone structure. In view of Johnson, et al, to fabricate the one piece prosthesis of Zang, et al out of two pieces would have been obvious to one with ordinary skill in the art as the independent pieces allows the surgeon greater flexibility.

Claims 8-11 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al as applied to claim 1 above, and further in view of Carignan, et al (4955916).

The insert of Zang et al is shown to be mechanically fixed to the fastening element. Carignan et al shows the same fixation of the insert to the fastening element using a morse taper connection. To connect the insert to the fastening element of Zang, et al with a morse taper connection would have been obvious to one with ordinary skill in the art as being essentially equivalent means for fixing an insert to a main component.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is

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(571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
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